EXHIBIT 18

PARK JENSEN BENNETT LLP

To: Lisa Landau, Esq.
Chief, Health Care Bureau
Office of the Attorney General of the State of New York

Maria A. Barton, Esq.
Senior Vice President, General Counsel
Purdue Pharma L.P.

Danielle Gentin Stock, Esq.
Head of Government Litigation and Investigations
Purdue Pharma L.P.

From: Douglas R. Jensen
Tami Stark

Subject: Auditor's Second Report on Purdue Pharma's ADD Program

Date: October 20, 2017

On October 7, 2016, the Auditor, Douglas R. Jensen, submitted his first report (the "Initial Report") under the Assurance of Discontinuance agreement executed on August 19, 2015 by Purdue Pharma L.P. ("Purdue") and the Office of the Attorney General of the State of New York ("OAG") (the "AOD"). That Initial Report covered the period from the effective date of the AOD through the date of June 22, 2016 (the "First Review Period").

This constitutes the second report of the Auditor pursuant to paragraph 41.c. of the AOD (the "Second Report"),[1] and covers the period from June 23, 2016 through June 30, 2017 (the

[1] The Auditor previously submitted its Report for the Second Review Period on September 8, 2017 (the "September 8 Report"). Since that time, it has determined that the Report contained small numerical errors (for example, stating that the number of New York HCPs placed on the

"Second Review Period"). The Report is divided into four parts: (I) summary of findings; (II) description of the scope of the Auditor's activities to date; (III) the Auditor's findings with respect to Purdue's compliance with Section IV.A. of the AOD and the reasonableness of its determinations whether to continue marketing opioid products to health care providers who were the subject of ADD Reports ("HCPs"); and (IV) anticipated next steps and process improvements.

I. Summary of Findings

The Auditor's work has continued to focus on two broad questions: first, whether Purdue is managing its ADD Program in compliance with Section IV.A. of the AOD; and second, whether Purdue's determinations regarding whether to continue marketing to HCPs subject to ADD Reports were reasonable.

As to the first question, the evidence reviewed by the Auditor and the Auditor's interactions with its Law Department indicate that the Company continues to operate the ADD Program in compliance with Section IV.A. The Initial Report included a paragraph-by-paragraph description of the requirements posed by Section IV.A. and the Company's compliance with those requirements. Since that time, the Company has instituted certain

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No-Call List because of sales force field observations was 5, when the correct number was 6) and obtained additional information from the Company that the Auditor believes should be brought to the OAG's attention (see footnote number 3 below). Also, in analyzing that additional information, the Auditor posed a number of questions to the Company, some of which led it to reclassify HCPs from one category of No-Call to another, for example, from "automatic" No-Call to one based on Law Department review (although such reclassifications did not result in the placement of any additional HCPs on the No-Call List). Because of these developments, the Auditor submits this Report to revise and supplement the September 8 Report.

changes and improvements to the ADD program. Rather than repeat the paragraph-by-paragraph analysis of the Initial Report, this Report will describe those changes and improvements, and concludes that they are consistent with the requirements of the AOD.

As to the second question, the Auditor concludes that the Company's determinations whether to continue marketing were reasonable. During the Second Review Period: we received from the Company a total of 261 ADD Files[2] (nationwide). Of those 261 Files, the Law Department ultimately determined to cease calling 236 of the HCPs, to continue calling 23 of the HCPs, and place 2 HCPs under review (which effectively means that the HCPs go back on the No-Call List while the Law Department continues its investigation).[3] The Auditor again focused

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[2] See Section II below for definition of the term "ADD File."

[3] It is important to note that, in addition to the 236 HCPs placed on the No-Call List in connection with the above 261 ADD Files, the Auditor recently learned that the Company also placed a substantial number of HCPs -- 367 -- on the No-Call List in circumstances where no ADD report was submitted and the Law Department conducted no substantive investigation of the HCP. When the Company learned from its media report and licensing database searches (see discussion below at Section III.A.1.) that an HCP had been charged with criminal activity or his medical license had been suspended, the Company placed that HCP on the No-Call List without further review or investigation (other than to confirm, for example, that the HCP's license had in fact been suspended). For purposes of this Report, we will refer to these 367 HCPs as the "Public Database Automatic Placements."

Because the Public Database Automatic Placements did not involve any exercise of judgment by the Legal Department, the Company did not include them in the quarterly spreadsheets that it provided to the Auditor. However, it did include such Placements -- at least for New York HCPs (the "New York Public Database Automatic Placements") -- in the monthly reports that the Company provided to the OAG. When the Auditor noticed that these New York Public Database Automatic Placements were not included in the quarterly spreadsheets that it had been receiving from the Company, the Auditor inquired further and thereby learned of the nationwide body of 367 Public Database Automatic Placements.

most of its attention on those HCPs placed in the continue calling category, and found the Law Department's determinations reasonable.

As before, the Auditor's evaluations, as well as the Company's determinations, constitute judgment calls that took different forms. In most instances, the Auditor immediately agreed with the Law Department's determination with little need for follow-up. In some instances, the Auditor raised questions about the Law Department's initial determination, as a result of which the Law Department gave further consideration to the HCP and either placed the HCP on the No-Call List or under review.[4] And finally, for two HCPs the Auditor found the Law Department's determination reasonable, but again brings them to the Attorney General's attention as a separate category because they raise issues of possibly broader application (see discussion below at Section III.B.3.). In all cases, however, based on our interactions with the Law Department, it has approached these determinations conscientiously.

As you know, during the First Review Period no ADD Reports resulted from field observations made by the Company's sales force in New York. That was a source of some concern for the OAG, which requested the Auditor to investigate possible explanations. As discussed in the Initial Report, the Auditor was unable to provide a definitive explanation, while observing that ADD Reports *had* resulted from sales force field observations in other parts of the

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We have discussed with the Company its decision not to include the Public Database Automatic Placements on the quarterly spreadsheets and, going forward, have requested that those Placements be included. Even if such Placements involved no exercise of discretion by either the sales force or the Law Department, we believe that they are important to understanding the overall performance of the ADD program.

[4] The Company changed its classification with respect to 6 of those HCPs, placing 4 of them on the No-Call List and subjecting 2 of them to further review.

country, and the Auditor found no evidence that Purdue was treating the State of New York any differently than other regions. In any event, to the extent the absence of New York field observation reports during the First Review Period was an anomaly, the Second Review Period has changed that, as 6 of the 39 New York HCPs listed on Purdue's monthly updates to the OAG were based on sales force field observations.[5] Upon review, the Law Department determined to keep all 6 of those HCPs on the No-Call List.

II. Scope of Activities

The Auditor's Role is defined by Paragraph 41.b. of the AOD and requires the Auditor to submit a report for each year of its three-year engagement. Although the second anniversary of the AOD's effective date was August 19, 2017, the parties agreed to extend the deadline for the Second Report to September 8, 2017.

Since the submission of the Initial Report on October 7, 2016, the Auditor has continued to receive extensive documentation from the Company, including: revisions to Purdue's Abuse

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[5] The Auditor's September 8 Report stated that the number of New York HCPs placed on the No-Call List because of sales force field observations was five. Since submitting the September 8 Report, however, the Auditor learned that Dr. John Sciales, a New York HCP, was also placed on the No-Call List based on sales force field observations. While Purdue had listed Dr. Sciales' name on its monthly report to OAG, it had mistakenly left his name off the quarterly spreadsheets provided to the Auditor.

Purdue provided the Auditor with ADD Files for these 6 New York HCPs, all of whom were placed on the No-Call List because of sales force field observations. Purdue also provided the Auditor with an ADD File for one additional New York HCP, Dr. Martin Tesher, who initially came to the attention of the Law Department from a news report. In total, then, the Auditor received 7 ADD Files for New York HCPs. The other 32 New York HCPs listed in Purdue's monthly reports to the OAG were placed on the No-Call List because of media reports and/or licensing database searches – in other words, they were New York Public Database Automatic Placements as defined above in footnote 3, and discussed below in Section III.A.1.

& Diversion Detection Standard Operating Procedure 1.7.1 ("ADD SOP"); Purdue's monthly updates to the OAG; revisions to Purdue's Sales Training Presentation and Quiz for the ADD Program; spreadsheets listing new hires who completed trainings and quizzes; a spreadsheet reflecting whether the sales representatives asked HCPs the Risk Evaluation and Mitigation Strategy ("REMS") compliance training questions and whether they provided the informational handout; Incentive Compensation Guides for the last quarter of 2016 and the first two quarters of 2017; and a spreadsheet of No-Call notifications listing instances in which calls were made on No-Call HCPs. In addition, the Auditor interviewed three members of the New York sales force, among other reasons to evaluate the employees' awareness of their ADD obligations.

The Auditor also had several interactions with the lawyers at Purdue having primary responsibility for the ADD Program: Maria A. Barton, Senior Vice President, General Counsel; Danielle Gentin Stock, Head of Government Litigation and Investigations; Stephanie DiFazio, Senior Counsel, Regulatory; and [redacted] Legal Analyst. The Auditor met with Ms. Barton, Ms. Stock and [redacted] in May 2017, and in the following months had conference calls and exchanged emails with one or more of them to discuss issues raised by the Auditor's review of the documents.

A principle focus of the Auditor's efforts, of course, was to evaluate the reasonableness of Purdue's decisions whether to continue promoting opioid products to the HCPs at issue in each ADD Report. With respect to that effort, as noted above Purdue provided the Auditor with 261 ADD Files closed during the Second Review Period. The term "ADD Files" includes the following four categories: (a) instances (239) in which a sales representative filed an ADD

Report;[6] (b) instances (4) in which a sales representative filed a request to resume calling on an HCP; (c) instances (16) in which a Company department other than the sales department reported conduct that led to the filing of an ADD Report;[7] and (d) instances (2) in which a news report raised issues about an HCP, but those issues did not require an automatic placement on the No-Call List, and the Law Department conducted further investigation.[8] Of these 261 ADD Files, as noted above (see footnote 5) seven concerned HCPs located in New York, and 254 concerned HCPs located in other states.

As with its Initial Report, the Auditor again determined to focus its efforts on those instances in which the Law Department decided to continue calling on the HCP. The Auditor

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[6] In a significant number of instances -- 142 -- sales representatives filed ADD Reports for HCPs who otherwise could have been placed on the No-Call List even absent such a Report, for example, where: (a) Purdue's public database search *also* indicated that the HCP had been suspended or made subject to criminal charges (in which case the Company could have classified the HCP as a Public Database Automatic Placement); or (b) the HCP had retired. However, because the sales representatives had filed ADD Reports as to such HCPs, the Company decided to record these instances in the category that captured filings of ADD Reports, and provided the Auditor with the ADD Files for these HCPs.

[7] For instance, the Customer Service Department notified the Law Department that one HCP lost his ability to submit insurance for Medicare, Medicaid and all other Federal Health care programs for three years. The Law Department investigated this HCP and found a *qui tam* lawsuit against him and 14 other HCPs. The lawsuit alleges that the 15 HCPs engaged in a scheme to refer patients in exchange for kickbacks. Purdue placed all 15 on the No-Call List.

[8] These two instances thus differ from the Public Database Automatic Placements discussed above. In the latter instances, the news report or database search indicated that the HCP had been charged with a crime or had his license suspended, and therefore the placement of the HCP on the No-Call List was automatic. In these two instances, the news report did not rise to that level of seriousness, and accordingly the Law Department conducted further review.

typically reviewed: the ADD Report or Request to Resume Calling; a DEA license screenshot; a state medical board license screenshot; opioid prescription statistics; and Call Notes written by the sales representatives after any visits to the HCP. In addition, some folders contain copies of news articles or state medical board licensing documents concerning the HCP. Further, as described in the Initial Report, for each HCP Purdue determined to continue to call, Purdue provided the Auditor with factual summaries. These summaries describe the source of the report, summarize the Law Department or outside counsel's conversations with the sales representatives and the status of the HCP's medical licenses, prescription history and other relevant facts.

III. Findings

A. *Purdue's Maintenance of the ADD Program*

To evaluate the Company's compliance with Section IV.A., the Initial Report included a paragraph-by-paragraph discussion of that Section. As noted above, this Report discusses changes and improvements Purdue has made to its ADD program since the Initial Report, explains how Purdue has addressed issues identified during the First Review Period, and summarizes the Auditor's findings from its interviews of a sample group of New York sales personnel.

1. Changes and Improvements to the ADD Program Since the Initial Report

Since the Initial Report, Purdue elevated Maria Barton to the General Counsel role and reorganized the Law Department. In January 2017, Associate General Counsel [redacted]

[redacted], and Senior Attorney [redacted], were let go as part of this reorganization.[9] Ms. Barton hired Danielle Gentin Stock as the Head of Government Litigation and Investigations, and placed her in charge of the Law Department's ADD Program responsibilities. Ms. Stock is a former Assistant United States Attorney from the Southern District of New York and subsequently served in Pfizer's Litigation Group. Stephanie DiFazio, Senior Counsel, Regulatory, and [redacted] Legal Analyst, assist with these responsibilities.

Approximately halfway through the Second Review Period, the Law Department retained an outside law firm, Spears Manning LLC, to conduct the first stage of the ADD investigations. Spears Manning is a small firm based in Southport, Connecticut that focuses its practice on government investigations, and related criminal and civil litigation. The lead attorney on the engagement is Brian Spears, a former federal prosecutor in the District of Connecticut. Upon review of the ADD Reports and conducting follow-up investigation, Mr. Spears makes a privileged recommendation to the Law Department to: 1) cease calling; 2) continue calling; or 3) continue calling and investigate again in six to twelve months. Ms. Stock reviews these privileged recommendations and makes the final decision. Sometimes, Ms. Barton also reviews the recommendations.[10]

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[9] While Purdue would not share with the Auditor the specific reasons for ending the employment of Ms. [redacted] and Ms. [redacted], it has indicated the decision was part of a broader corporate reorganization, and did not stem from any finding of malfeasance relating to the ADD program.

[10] The use of outside counsel to conduct the first stage of ADD investigations is of course a significant change from the process employed by Purdue during the First Review Period. As we read the AOD, however, it does not preclude the use of outside counsel in this advisory role, so long as the final determinations are made by the Law Department. Paragraph 31.b. of the AOD

If a determination is made to continue calling the HCP, the Law Department sends the Auditor a factual summary reflecting the facts gathered during these investigations. A contract attorney creates the factual summaries based on the privileged memoranda drafted by Spears Manning, and Ms. DiFazio and [redacted] review them before they are sent to the Auditor.

In the Initial Report, the Auditor recommended that the Law Department: (1) prepare the factual summaries contemporaneously with its determinations; (2) ensure that the factual summaries reflect all the facts relevant to the Law Department's determinations; and (3) institute a check off system with respect to the factual summaries, which would reflect that both attorneys involved in the review process have initialed the fact summaries to indicate their approval. The Auditor felt that these enhancements would strengthen both the Law Department's determination process and the Auditor's evaluation of the results. Based upon its review of the factual summaries submitted since Purdue retained Spears Manning, the Auditor believes that the summaries comply with these recommendations.

Since the Initial Report, Purdue also began to use an automated system called Vinyl, which scans news, state and DEA licensing databases and other online media for the names of the HCPs in Purdue's Phoenix system. Purdue had previously retrieved the names of HCPs cited in news articles and then had to manually determine whether those names appeared in the Phoenix system. If Vinyl finds a match, Purdue's Ethics and Compliance Department

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provides that Purdue may resume calling on an HCP only after the "Law Department, in writing, reasonably concludes, based on available information, that it is appropriate . . . ." Here, while outside counsel makes a recommendation to the Company, the Law Department makes the final decision.

("Compliance Department") is automatically notified. Accordingly, ADD Files can originate from Vinyl, the sales force, or other sources.

In addition, Purdue revised its ADD SOP to have such notifications and sales force ADD Reports sent directly to its Compliance Department. The Compliance Department forwards any ADD Reports that require legal investigations to the Law Department. Only automatic determinations to place an HCP on the No-Call List are not forwarded to the Law Department.

Further, Purdue has revised its ADD SOP to clarify the steps the Compliance Department must follow when they discover a Call Note that raises an ADD concern, but the sales representative failed to file an ADD Report. In these instances, the Compliance Department will contact the sales person who was responsible for the Call Note and request that he or she submit an ADD Report. The Compliance Department will forward any ADD Report that is not automatic to the Law Department.

Purdue also continues to provide and track training with respect to the ADD program. On February 1, 2017, Purdue moved from live training to computer based training for new hires in the sales force and provided the Auditor with spreadsheets listing every new hire who completed the training and quiz. During the training, Purdue introduced a new policy that the sales force may request to resume calling on a No-Call HCP no earlier than two years after the HCP was placed on the No-Call List. Purdue plans to include this new policy in a revised Working Practice Document for the Compliance and Law Departments.

Finally, Purdue continues to educate HCPs about the risks of prescribing opioids. As per Section IV.C. of the AOD, starting in January 2016, Purdue required all sales representatives on

their first visit to ask whether the HCP has completed REMS-compliance training.[11] If the HCP indicates that the training has not been completed, the sales representative must provide that HCP with a REMS-compliant informational handout. Further, beginning in January 2016, any sales representative asked by a New York HCP about addiction treatment is required to provide the HCP a New York State Office of Alcoholism and Substance Abuse Services brochure. During the Second Review Period, Purdue provided 103 of those brochures.

2. Issues Identified during the First Review Period

Since the Initial Report, the Auditor has followed up with Purdue on certain specific questions identified and discussed in that Report. Those issues are discussed below.

Paragraph 29 of Section IV.A. requires that ADD Reports be filed when ADD Covered Persons observe or learn "(b) facts suggesting that an HCP's patients are seeking opioids for misuse, including for example an HCP who has failed to comply with NY's I-STOP Program." During the First Review Period, while Purdue had included this requirement in its ADD SOP, it had not seen any examples of ADD Reports filed because an HCP had failed to comply with NY's I-STOP program. During the Second Review Period, Purdue again has not found any examples of ADD Reports that were based on a failure to comply with I-STOP.

Paragraph 31.a. of Section IV.A. requires in part that to the extent a sales representative "promotes a Purdue opioid product on a planned call to an HCP on the No-Call List," such sales representative shall be subject to potential discipline. As noted in the Initial Report, if a sales

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[11] While paragraph 41 of the AOD only requires the Auditor to evaluate Purdue's compliance with Section IV.A. of the AOD, during the Second Review Period Purdue also provided the Auditor with information regarding its compliance with Section IV.C. of the AOD.

representative were to have contact with an HCP on the No-Call List and enter such contact in the Call Notes, the Phoenix system generates a notification of that fact to the Law Department. In such instance, the Law Department investigates to determine the reason for the contact and pursues appropriate follow-up. Pursuant to our request, the Law Department provided a spreadsheet reflecting the reasons for these notifications and their disposition by the Law Department. That spreadsheet covered the period of September 16, 2016 through July 12, 2017, during which the Law Department received notifications of 50 such instances.[12]

As with the First Review Period, the Auditor found that the reasons for such contact vary, but found no instances in which a sales representative intentionally visited a No-Call HCP for the purpose of marketing to that HCP. In some instances, a sales representative inadvertently encountered a No-Call HCP during a visit to another (unrestricted) HCP practicing in the same medical office, and consistent with ADD procedure the sales representative noted the encounter in her Call Notes after the fact. In other instances, the Law Department directed a sales representative to visit a No-Call HCP's office as part of its investigation. In one case, a sales representative missed the email sent the day before stating that the HCP had been placed on the No-Call List. This sales representative was reminded of the policy and coached on the requirements of the ADD program. For a short period (after the Initial Report through early spring 2017), the Law Department decided to allow sales representatives to visit No-Call HCPs to educate them on addiction or screening tools. The Law Department decided to end this practice after Ms. Stock's hiring in or about April 2017.

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12 As discussed in the Auditor's Initial Report, for the period from January 1, 2016 through September 15, 2016 Purdue reported 24 such instances.

Paragraph 31.d. of Section IV.A. requires Purdue to maintain other methods of identifying potential abuse such as: "(ii) examining data sources, such as HCP's prescription history, to identify HCPs who should [be] reviewed for potential placement on the No-Call List."

Purdue has attempted to identify such sources, but has so far been unsuccessful. For instance, the Company tried to analyze increases in volumes of prescriptions for HCPs, but encountered false positives; because the Company does not have access to data on patient numbers, it cannot tell whether an HCP's prescriptions have increased because the HCP is seeing more patients or because the HCP is prescribing more to the same patients. Purdue investigated outside vendors, but found that such vendors would require Purdue to purchase not only the vendors' algorithmic tools, but also external data streams from third parties, and the cost could amount to several millions of dollars annually. Further, Purdue was not convinced the end product would be definitive, because the Company would have to take into account additional criteria not considered by the algorithm (such as the specialty of the HCP, or whether the prescriber was a Medical Doctor or Nurse Practitioner).

Paragraph 31.e. of Section IV.A. requires that performance evaluations of marketing employees "shall meaningfully take into account that sales persons inform HCPs . . . about [opioids'] potential for abuse and diversion, and how to minimize those risks."

Before the Initial Report, the Company informed the Auditor that it intended to implement a process for the next performance cycle to have any discipline of sales representatives provided to managers prior to their completion of performance reviews as a reminder that this issue needs to be addressed in the performance review. Since that Report, the Law Department has informed us that Purdue's Employee Manual has been amended to provide

that adherence to Purdue's policies will be considered at performance evaluations. Further, all sales force reviews for 2017 contain the following questions: "i) Employee Compliance Question: In the past year, have you received compliance-related discipline such as a written warning? YES or NO; if yes, describe; and ii) Manager Question: Except as otherwise described above by employee, has your team member received a compliance-related discipline such as a written warning? YES or NO; if yes, describe."

Paragraph 31.f. of Section IV.A. requires that if a sales representative fails to file an ADD report when appropriate, that "person shall be subject to disciplinary action by Purdue, including but not limited to censure, probation and termination." During the Second Review Period, Purdue reported one instance of discipline. The Company issued a warning letter to a sales representative who had called on two HCPs who demonstrated unusual changes in their prescribing habits, but failed to file an ADD report. The HCPs were eventually placed on the No-Call List because of arrests and/or prosecutions.

In addition to the issuance of the warning letter, the Compliance Department reviewed the ADD SOP with the sales representative and discussed various scenarios under which the policy might require submission of an ADD Report. The Department also instructed the sales representative on the need to report situations where prescribers have a sudden unexplained change in their prescribing or dispensing patterns that are not accounted for by changes in patient numbers or practice type. They also reminded the sales representative of additional training requirements.

Paragraph 32 of Section IV.A. has two components. First, the paragraph requires that "ADD Covered Persons in New York shall enter detailed call notes regarding sales calls to

HCPs in which compliance or potential abuse issues are raised." Second, the Company's Compliance Department "shall, on a quarterly basis, audit and review a sample of such call notes to, inter alia, evaluate compliance with the ADD Program and determine whether ADD Reports need to be filed regarding particular HCPs." As mentioned above, Purdue revised its ADD SOP to clarify the steps the Compliance Department must follow when they discover a Call Note that raises an ADD concern, but an ADD Report was not filed. In these instances, the Compliance Department will contact the sales person who was responsible for the Call Note and request that he or she submit an ADD Report. The Compliance Department will forward any ADD Report that is not automatic to the Law Department. Since the Initial Report, the Law Department has informed the Auditor that the Compliance Department has not found any Call Notes which reflect ADD concerns that were not flagged in an ADD report.

Paragraph 33 of Section IV.A. requires that, in Purdue's compensation structure for marketing employees, no more than 30% of an individual's total compensation (including bonus) may be based on the volume of OxyContin prescriptions. Since the Initial Report, based upon Purdue's Incentive Compensation Guides, Purdue has simplified its incentive compensation structure. The sales force receives 70% of its compensation in a base salary and 30% in variable incentive compensation. The variable incentive compensation consists of: 70% based on sales of Hysingla and Butrans; 15% based on sales of Oxycontin; and 15% based on doctor evaluations provided through a third-party vendor.

3. Interview of New York Sales Personnel

As mentioned in the Initial Report, the Auditor planned to schedule interviews with members of the New York sales force to evaluate their awareness of their ADD obligations. In

April, the Auditor interviewed three such members: a sales representative (Purdue calls them "Territory Business Managers" or "TBMs"), a supervisor to sales representatives ("District Business Manager" or "DBM"), and a TBM, who at the time was acting as a DBM. The Auditor found all three employees to be aware of their ADD obligations.

The Auditor interviewed Gabe Fischer, a TBM with responsibility for a region east of Syracuse in Upstate New York. Mr. Fischer described the ADD program as a process Purdue put in place to educate the sales force and help them determine if something is not right with their customers. Mr. Fischer explained in detail how the Phoenix system works and how he must check that system to determine if a customer/HCP is on the No-Call List before calling on the HCP. He also described how he had reported through Phoenix an ADD concern regarding an HCP from Dolgeville, New York, and was able to recite the bases for recommending that an HCP go on the No-Call List.

In addition, Mr. Fischer stated that he advises HCPs of the risks of prescribing opioids on a daily basis, but doesn't discuss New York's I-STOP program much anymore because it has existed for some time and, as far as he can tell, HCPs are using it on a regular basis. When asked why the Company had not seen many ADD Reports filed by New York sales representatives as a result of field observations, he speculated that his approximately 100 sales targets have already been heavily scrutinized and, because the sales representatives speak so often about risks, the providers are now very responsible.

The Auditor also interviewed Mr. Fischer's supervisor, Kim Fear, a DBM for Upstate New York and parts of Eastern Pennsylvania. She manages 6 TBMs in New York and 3 in

Pennsylvania who call on between approximately 100 and 150 HCPs a quarter. She reports to a Regional Business Manager, who is located on Long Island and is responsible for the Northeast.

Ms. Fear described the main purpose of the ADD program as ensuring that Purdue is promoting opioid products appropriately and not to prescribers who give rise to a concern of misuse or diversion. Ms. Fear appeared to have a clear understanding of how HCPs are placed on the No-Call List, how ADD concerns are identified in Phoenix and the various bases for an ADD concern. When asked why the Company had not seen many ADD Reports based on New York sales force field observations, she speculated that may be because she and her TBMs are vigilant in educating the HCPs they call on and talk about the risks of addiction, abuse and misuse every time they discuss the products. Ms. Fear reviews her TBMs' Call Notes and has never found anything that has led her to believe that they should have filed an ADD report when they had not.

The Auditor also interviewed Jennifer Monasterio, who, at the time, was a TBM and acting as the DBM for Queens and Eastern Nassau County on Long Island. She reported to the same Regional Business Manager as Kim Fear. When asked to explain the purpose of the ADD program, Ms. Monasterio explained in substance that: if there is an HCP she is calling on and she believes from what she hears and sees that the HCP could be prescribing for the wrong reasons, she should gather all the information she can about the HCP and let the Law Department know she is uncomfortable supporting the doctor because there may be illegal activity; the Law Department then decides whether to allow the sales force to continue to call or not.

Ms. Monasterio appeared to have a clear understanding of how the ADD program works through the Phoenix system and the bases for placing an HCP on the No-Call List. She stated

that she had put a number of HCPs on the No-Call List, and recounted how she had recently submitted ADD Reports about an HCP who was prescribing Roxicodone and an HCP who was prescribing extended release Tramadol. She believes both products are subject to abuse and correlate with a cash business so she wanted the Law Department to investigate the HCPs. She believed that at the time of the interview, the HCPs she had reported were still on the No-Call List.

B. Purdue's Decisions Regarding Whether to Continue Marketing During the Second Review Period

Pursuant to Paragraph 41.b. of the AOD, the Auditor obtained from Purdue each of the ADD Files closed during the Second Review Period. As noted above, during the Second Review Period, Purdue initially determined to cease calling 232 and to continue calling 29 of the HCPs. Following discussions with the Auditor and further consideration, the Company changed its classification with respect to 6 of those HCPs, and either placed them on the No-Call List (4) or is subjecting them to further review (2). Thus, in the final analysis, the Company determined to cease calling 236 HCPs, determined to continue calling 23 HCPs, and has 2 HCPs still "under review," which effectively means that the HCPs go back on the No-Call List while the Law Department continues its investigation.

As required by the AOD, the Auditor has evaluated the reasonableness of the Company's determinations. In doing so, the Auditor applied the guidelines outlined in the Initial Report. (*See* pages 25-27 of the Initial Report.) As in the Initial Report, this Report does not discuss every determination made by the Company, but instead discusses those which we believe to be representative. Our evaluations of those determinations again fall into three categories: (a)

instances in which the Auditor found the Company's determination to continue calling reasonable; (b) instances in which the Company initially determined to continue calling, and then after discussion with the Auditor and further reconsideration determined to cease calling; and (c) instances in which the Auditor found the Company's determination to continue calling reasonable, but which were closer calls and raised issues of possibly broader application that the Auditor wished to bring to the OAG's attention. Each of these categories is discussed below in turn.

1. *Continued-Calling Determinations Found Reasonable*

Selected examples of the Company's determinations to continue calling, and how the Company arrived at them, are described below.

Dr. Harvey Siegel. On or about January 18, 2017, a Purdue sales representative filed an ADD Report with respect to Dr. Harvey Siegel, an osteopathic physician located in Succasunna, New Jersey. The Report was filed by the sales representative who calls on Dr. Sharma. This sales representative said that Dr. Siegel told him he had been visited by the New Jersey Medical Board, who asked him a few questions, but he was not charged with any wrongdoing.

In response to the Report, the Law Department spoke with the sales representative who made the Report and has been calling on Dr. Siegel for almost 30 years. The sales representative reported that the New Jersey Medical Board asked Dr. Siegel questions about his prescription of opioids for a specific patient. Dr. Siegel explained the reasons for the prescription and the Medical Board did not ask anything else. After making the ADD report, the sales representative ran into Dr. Siegel in the supermarket and he mentioned that he had not heard anything further from the Medical Board.

In addition, the sales representative reported that in his view Dr. Siegel is competent and knowledgeable. He has a certification in pain management, but he also outsources to a pain management specialist. He is open to education, monitors his patients with drug testing and screening, and understands the risks of opioid addiction.

In addition to contacting the sales representatives, the Law Department reviewed the Call Notes, Dr. Siegel's medical license (which was active), his DEA registration (active), and his prescribing history (during 2017, his opioid prescriptions trended down from a high of 180 per month to a low of 90), and located no publicly available negative information. Based on all the above, the Law Department determined that it was appropriate to continue calling on Dr. Siegel.

Dr. Robert Sindel. On or about August 19, 2016, a Purdue sales representative filed an ADD Report with respect to Dr. Robert Sindel, an Internist located in St. Louis, Missouri. The Report was based upon Dr. Sindel reporting to the sales representative that his prescription system had been hacked and two fraudulent prescriptions for morphine had appeared in his system.

In response to the Report, the Law Department spoke with the sales representative who filed the ADD Report. She said that after discovering the apparently fraudulent prescriptions, Dr. Sindel said he called the DEA, but had not heard back yet. She suggested that he report the incident to the local authorities and he said he would. She also explained to the Law Department that she has been calling on Dr. Sindel for 11 years and never noticed any suspicious conduct relating to his prescribing.

In addition to contacting the sales representative, the Law Department reviewed the Call Notes, Dr. Sindel's medical license (which was active), his DEA registration (active), his

prescribing history (which showed a low number of prescriptions per month), and located no publicly available negative information. Based on all the above, the Law Department determined that it was appropriate to continue calling on Dr. Sindel, but to re-review him in 6 to 12 months to determine if further follow-up was necessary.

Dr. Gary Child. On or about August 9, 2016, a Purdue sales representative filed an ADD Report with respect to Dr. Gary Child, an osteopathic physician located in Murray, Utah, who runs the Utah Pain Relief Institute ("UPRI"). The Report was based upon another HCP informing the sale representative who calls on Dr. Child that Dr. Child had been served with 41 subpoenas relating to 41 patient deaths.

In response to the Report, Purdue's outside counsel, Spears Manning, spoke with the two sales representatives who call on Dr. Child. They stated that the complaints about Dr. Childs had originated with two employees from a different clinic who had formerly been employed by Dr. Child, and who had alleged that he had been served with the subpoenas and was committing Medicare fraud. The sales representatives believe that these two employees are not credible because they left the UPRI on bad terms and one of them is on Purdue's No-Call List. The sales representatives also had not learned anything about the alleged deaths from other sources. They checked the media reports and ran a Google search, but did not see anything to corroborate the Report.

Further, the sales representatives said that they did not have concerns about Dr. Child or UPRI. Dr. Child made a point to have his staff participate in an educational program organized by the sales representatives, uses a pill monitoring system, and has a urine screening process in

place. They also did not observe anything suspicious about the amount or type of patients Dr. Child is seeing.

In addition to contacting the two sales representatives, Spears Manning reviewed the Call Notes, Dr. Child's medical license (which was active), his DEA registration (active), his prescribing history (which showed opioid prescriptions at a high level (ranging between 400 and 900 per month) but without notable peaks or valleys, and at a level consistent with a pain management practice), and his online prescriber profile and medical license verification, and located no publicly available negative information. Based on all the above, the Law Department determined that it was appropriate to continue calling on Dr. Child, but to re-review him in 6 months to determine if further follow-up was necessary.

2. *Initial Determinations to Continue Calling Revisited and Changed Following Input from the Auditor*

As noted above, in some instances the Company initially decided to continue calling, and subsequently changed that determination after discussion with the Auditor and further consideration. Purdue changed 4 determinations from continue calling to cease calling and 2 determinations from continue calling to under review, which, as mentioned above, effectively means that the HCPs will go back on the No-Call List while the Law Department continues its investigation. Examples of those determinations, and how the Company arrived at them, are described below.

Dr. Michael Umerah. On or about August 10, 2016, a Purdue sales representative filed an ADD Report with respect to Dr. Michael Umerah, who specializes in physical medicine and rehabilitation, and maintains offices in Searcy and Little Rock, Arkansas. The Report was based

upon Dr. Umerah informing the sales representative who submitted the ADD report that someone reported him to the authorities for allegedly running a "pill mill." The doctor said that federal authorities came to the office and shut it down for the day. They also detained and questioned the patients in the waiting room.

In response to the Report, the Law Department spoke with two sales representatives and a manager (DBM), who did not report any concerns about Dr. Umerah. Four weeks after the ADD Report, the sales representative who filed the Report said that he had not heard any more about the incident. In addition to contacting the sales representatives, the Law Department reviewed the Call Notes, Dr. Umerah's medical license (which was active), his DEA registration (active), and his prescribing history. Based on all the above, the Law Department determined that it was appropriate to continue calling on Dr. Umerah.

While reviewing the prescription history, the Auditor noticed a steep increase in opioid prescriptions during 2016 and asked the Law Department whether there had been any additional feedback from the sales representatives. The Law Department re-reviewed Dr. Umerah and found that the Medical Board website now indicates that he has been found to be abusing prescriptions. Accordingly, the Law Department placed Dr. Umerah on the No-Call List.

Roy Waronsky. On or about November 30, 2016, a Purdue sales representative filed an ADD Report with respect to Roy Waronsky, a physician's assistant practicing pain management in Charlotte, North Carolina. The Report stated that the sales representative who calls on Mr. Waronsky attempted to make a call and was told by a receptionist at his practice that he had been "flagged" by the North Carolina Medical Board for over-prescribing opioids, such as OxyContin.

In response to the Report, Spears Manning spoke with two sales representatives, including the one who filed the Report. Both sales representatives explained that they did not have concerns about Mr. Waronsky's prescribing practices. Spears Manning also reviewed the Call Notes, Mr. Waronsky's medical license (which was active), his DEA registration (active), and his prescribing history, and located no publicly available negative information. Based on all the above, the Law Department determined that it was appropriate to continue calling on Mr. Waronsky.

While reviewing the prescription history, the Auditor noticed that in December 2016, shortly after the ADD Report, Mr. Waronsky suspended his opioid prescriptions and then resumed prescribing again in January 2017. The Auditor asked the Law Department to recheck the medical board website to confirm that no further action had been taken. The Law Department rechecked and found that Mr. Waronsky can no longer write prescriptions for controlled substances. Accordingly, the Law Department added him to the No-Call List.

Dr. John Sherrill. On or about July 23, 2016, a Purdue sales representative filed an ADD Report with respect to Dr. John Sherrill, an Internist in Rutherford College, North Carolina. The Report was based upon Dr. Sherrill's nurse expressing concern that patients might be diverting opioid products. Her concern stemmed from the fact that a patient (or former patient) was under investigation for selling prescription drugs. She also reported a rumor that several patients were not fully using all their medications and diverting the leftover pills.

In response to the Report, the Law Department spoke with two sales representatives and an Account Manager, who said that Dr. Sherrill is not regarded as a high prescriber of opioids. They have observed nothing at the practice to suggest any illegality or improper practices, and

were not aware of any overdoses by his patients or of any law enforcement investigation of his practice. In addition to contacting the sales representatives, the Law Department reviewed the Call Notes, Dr. Sherrill's medical license (which was active), his DEA registration (active), and his prescribing history. Based on all the above, the Law Department determined that it was appropriate to continue calling on Dr. Sherill.

While reviewing the Call Notes, the Auditor noticed a comment from July 2016 that Dr. Sherrill is prescribing Butrans to "noncompliant" patients. The Auditor asked the Law Department to ask the sales representatives about the Call Note and asked whether anyone has followed up again with the nurse about her concerns. The Law Department decided to place Dr. Sherill "under review," which means that he is now on the No-Call List pending further review.

3. *Determinations Found Reasonable, but Raising Issues for the OAG's Consideration.*

The Initial Report described several instances in which the Auditor found the Company's determination to continue calling reasonable, but the determination raised issues of more general application that the Auditor wished to bring to the OAG's attention.[13] During the Second Review Period, the Auditor found two such instances: in one instance, after raising this concern, Purdue changed the determination to cease calling; and in the second instance, after raising this

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[13] For example, one HCP's license was suspended for a personal substance abuse issue, but the suspension was waived because she was complying with certain conditions. While a personal substance abuse issue is obviously a red flag that merits attention, in the Auditor's view it did not represent an automatically disqualifying factor where the issue was controlled and the HCP did not currently present a significant risk of illegal overprescribing to others. (*See* pages 34-35 of the Initial Report.)

concern, Purdue decided to maintain the continue calling status, but flag the HCP for another review in 6 to 12 months.

Dr. John Dulemba. On or about May 19, 2016, a Purdue sales representative filed an ADD Report with respect to Dr. John Dulemba, a gynecologist located in Denton, Texas. The sales representative reported that Dr. Dulemba informed him that a pharmacist reported him to the Texas Medical Board because the pharmacist claimed the medications he was prescribing were "too much narcotics" and outside of the doctor's specialty. Dr. Dulemba also stated he was now under investigation by the medical board.

In response to the Report, the Law Department spoke with the sales representative who filed the Report and he stated that, while Dr. Dulemba is a gynecologist, his practice specializes in handling pelvic pain. The pharmacist had questioned a prescription for one patient and Dr. Dulemba stated to the reporting sales representative that he had sufficient supporting documentation for the prescription for that patient. The Law Department also reviewed the Call Notes, Dr. Dulemba's medical license (which was active), his DEA registration (active), and his prescribing history (which was trending down since the beginning of 2016), and located no publicly available negative information. Based on this, the Law Department determined that it was appropriate to continue calling on Dr. Dulemba, but re-review him in 6 to 12 months.

The Law Department also provided the Auditor with documents that showed that Dr. Dulemba was disciplined twice by the Texas Medical Board: in 2011 for prescribing pain narcotics to himself; and in 2015 for failing to document his rationale for prescribing pain medication. In light of this, the Auditor informed the Law Department that it considered their determination to continue calling reasonable, but would flag it for consideration by the OAG.

Any time an HCP is disciplined for conduct relating to prescribing controlled substances, such discipline goes to the heart of the AOD. On the other hand, it does not in the Auditor's view represent an automatically disqualifying factor so long as the issues are addressed and controlled. The Law Department, however, then decided to place Dr. Dulemba on the No-Call List.

Dr. Danny Silver. On or about February 15, 2017, a Purdue sales representative filed an ADD Report with respect to Dr. Danny Silver, who specializes in family medicine in Fort Smith, Arkansas. A sales representative reported that Dr. Silver may have had his license suspended and that another doctor in the practice was seeing his patients.

In response to the Report, Spears Manning spoke with two sales representatives and their supervisor, who said the patient base appeared appropriate, Dr. Silver screens patients to make sure they do not abuse or divert medication, and he has an independent consultant on site who does all the practice's drug screening. The sales representative who filed the Report also explained that she had heard about the potential suspension third-hand. Spears Manning also reviewed the Call Notes, Dr. Silver's medical license (which was active), his DEA registration (active), and his prescribing history, and located no publicly available negative information. Based on all the above, the Law Department determined that it was appropriate to continue calling on Dr. Silver.

The Auditor noticed that the Detailed License Verification indicated that Dr. Silver had been disciplined in North Carolina in 2006 and in Arkansas in 2010. The Auditor asked the Law Department for any documents relating to this discipline. The documents showed that in 2010, the Arkansas Medical Board charged Dr. Silver with overprescribing controlled medications to patients, and ordered him to stop accepting new chronic pain patients until he completed training

and submitted a protocol for prescribing Schedule medications. In 2014, Arkansas held a hearing to determine if he had overprescribed controlled medications, but it did not result in a finding of a violation.

Based on this, the Auditor informed the Law Department it found the determination to continue calling reasonable, but it would be flagged for the OAG. Again, while any discipline relating to opioid prescriptions implicates the AOD, Dr. Silver has active medical licenses and appears to have corrected the behavior. The Law Department reviewed Dr. Silver and found no new discipline cited on his medical license. Accordingly, they decided to continue calling on this HCP, but will review him again in 6 to 12 months.

V. Prospective Plan of Action

In the upcoming review period, the Auditor plans to continue evaluating Purdue's Compliance with AOD Section IV.A. In particular, the Auditor will continue to evaluate Purdue's determinations regarding ADD Reports on a quarterly basis and will provide feedback throughout the review period on how to improve that process.